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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/877,374 | 06/08/2001 | Jeffrey C. Rapp | AVI-007N | 2448 |
| 26739 7590 09/30/2008 AVIGENICS, INC. 111 RIVERBEND ROAD ATHENS, GA 30605 | | | | |
| EXAMINER TON, THAIAN N | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/877,374 | Applicant(s) RAPP, JEFFREY C. | |
| | Examiner Thaian N. Ton | Art Unit 1632 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/13/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-29,62-70,72,74 and 75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-29,62-70,72,74 and 75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____. 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____. |
|--|--|

DETAILED ACTION

Applicants' Response and Amendment, filed 6/13/08, has been entered. Claims 74 and 75 are newly added; claims 1-5, 9-29, 62-70, 72, 74 and 75 are pending and under current examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-17, 19-29, 62, 63 and newly added claim 74 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. as further evidenced by WO 99/19472 (published April 22, 1999). This rejection is maintained for reasons of record.

Examiner's Note. Applicants' have now added claim 74, which recites the limitation that the oviduct cell is a magnum cell. The art of Sanders teaches using tubular gland cells, which are primary oviduct cells (see p. 6551, 1st col., 1st ¶). The '472 document is provided as evidence that tubular gland cells are found in the magnum of the oviduct, and thus, would be considered magnum cells. See, for example, p. 7, lines 19-20, p. 9, lines 29-30, which recite "tubular gland cells of the magnum of the oviduct." Accordingly, the cells taught by Sanders would be considered magnum cells, as evidenced by the '472 document.

Applicants' Arguments. Applicants argue that it has been determined that proteins produced in avian oviduct cells (i.e., tubular gland cells) are not fucosylated. Applicants provide Zhu (2005) and Raju et al (2000) and state that this lack of fucosylation in the oviduct cells of chickens is in

contrast to what is seen in other cells of the chicken. Applicants argue that this absence of fucose alters the therapeutic utility of monoclonal antibodies by increasing their potency, and provide Etches (2006) as support. Applicants argue that the feature that oviduct cells do not fucosylate proteins was not disclosed in the prior art references, and that the invention is more than the predictable use of prior art elements. See page 8 of the Response. Applicants argue that the Examiner is attempting to draw a nexus between language dictating the requirements for a finding of obviousness and what is required for showing of an improvement that is more than the predictable use of prior art elements according to their established function. Applicants argue that the Examiner is improperly attempting to use requirements for an affirmative showing of obviousness to prevent Applicants from submitting post-filing evidence of non-obviousness which was published after the filing of the application. Applicants submit that the post-filing evidence of Zhu and Etches has been properly submitted. See pages 8-9 of the Response.

Response to Arguments. These arguments have been considered, but are not persuasive. Zhu and Etches have been considered here and previously. Although these pieces of art may point to an increased potency in the antibodies that would be produced when utilizing oviduct cells of chickens, it is reiterated that the claims do not require increased potency, or any particular yield of antibody. There is no teaching in either Zhu or Etches that would lead one of skill in the art to believe that antibodies could not be produced using avian oviduct cells. With respect to Applicants' arguments with regard to what must be disclosed are found under 35 USC 112 (enablement and written description), the Examiner responds that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Additionally, the claims do not recite the increased potency that is suggested by Zhu and Etches, and finally, there is no suggestion in the prior art that one of

skill in the art could not reasonably produce a heterologous antibody by an avian oviduct cell, as the combined art teaches. Applicants have failed to distinguish their methods from those of the combined art, therefore, because the combined art provides the requisite teachings and motivation, it is maintained that this rejection is proper. Although Applicants do not need to recite the advantageous feature of the product that is produced by a method in a particular method claim, because Applicants' method steps result in a heterologous antibody, which is no more than what is taught in the art, the rejection is maintained.

With respect to Applicants' arguments regarding Raju (see pages 9-10 of the Response) the Examiner notes that although Raju teaches that serum of chickens were known at the time of the invention to contain fucose, this does not provide a nexus with regard to Applicants' invention, because Raju provide no guidance to show that there would be any unpredictability in producing monoclonal antibodies in avian oviduct cells. Additionally, Raju are not looking at the ability for avian oviduct cells to product monoclonal antibodies. Finally, it is noted that because Applicants' methods are not distinguished from that of the prior art, the combination of art is sufficient to render the claimed invention obvious. That is, there is no unexpected result in the production of a heterologous antibody utilizing an avian oviduct cell. Although the post filing art of Zhu may teach an increased potency in the resultant antibody, there is nothing in the claims that requires this increased potency, the claims merely require production of a heterologous antibody; therefore, the combined art of record would reasonably arrive at the claimed invention.

Applicants' Arguments. Applicants argue that the improvement of producing monoclonal antibodies in oviduct cells in culture is more than the predictable use of prior art elements according to their established function, since for one thing the increased potency of the monoclonal antibodies produced could not be predicted based upon the prior art (see p. 10 of the Response).

Response to Arguments. These arguments have been considered but are not persuasive. The claimed invention requires no increased potency, or an increased yield of antibodies, for example. The only requirement of the claims is for the production of a heterologous antibody by an avian oviduct cells. Applicants are arguing limitations that are not found within the claims (*e.g.*, increased potency of the resultant antibody). The Examiner reiterates that the method steps only require a single result – that of producing a heterologous antibody. The steps that are required of the claims are rendered obvious by the cited art of record. Accordingly, the prior rejection of record is maintained.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken with Sanders *et al.* in further view of Mohammed *et al.* and in further view of Michael *et al.* as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-17, 19-29, 62, 63 and newly added above, and further in view of Larocca *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Claims 64-70, 72 and newly added claim 75 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken Sanders, in further view of Mohammed, and in further view of Michael *et al.* as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-17, 19-29, 62, 63 and newly added claim 74 above, and further in view of Ling *et al.* and Najarfian *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632